Docket No.: PF-0321-2 DIV

Response Under 37 C.F.R. 1.116 - Expedited Procedure
Examining Group 1653

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Bandman et al.

Title: DISEASE ASSOCIATED PROTEIN KINASES

Serial No.: 09/769,970 Filing Date: January 24, 2001

Examiner: Carlson, K. Group Art Unit: 1653

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REPLY BRIEF ON APPEAL

Sir:

This is Appellants' Reply Brief On Appeal (submitted in triplicate) in response to the Examiner's Answer dated November 13, 2003 ("the Examiner's Answer") in the above-identified application.

In the Examiner's Answer the Patent Examiner maintained the rejection of Claims 24, 27-29, and 31 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description of the claimed polynucleotides encoding polypeptide variants and of the claimed polynucleotide variants.

WRITTEN DESCRIPTION REJECTION OF CLAIMS 24, 27-29, AND 31

I. Nowhere in the Examiner's Answer does the Examiner offer any evidence that one of ordinary skill in the art would not have understood, from the disclosure in the Specification, along with "[w]hat is conventional or well known to one of ordinary skill in the art," that Appellants were in possession of the claimed polynucleotide encoding a polypeptide comprising a naturally occurring amino acid sequence having at least 90% sequence identity to an amino acid sequence of SEQ ID NO:2 or the claimed polynucleotide comprising a naturally occurring

polynucleotide sequence having at least 90% sequence identity to a polynucleotide sequence of SEQ ID NO:9.

The Examiner alleged that "[w]ithout a statement regarding the activity of the polynucleotides encoding a polypeptide have [*sic*] 90% identity to SEQ ID NO:2 or polynucleotides that are 90% identical to SEQ ID NO:9 and encode a polypeptide having any function one skilled in the art cannot know the metes and bounds of the claimed polynucleotides." (Examiner's Answer, page 3.)

The Examiner discounts the claim limitations of "having at least 90% sequence identity to an amino acid sequence of SEQ ID NO:2" and "having at least 90% sequence identity to a polynucleotide sequence of SEQ ID NO:9" and attempts to introduce a limitation of "function" to the polypeptide variants and polynucleotide variants, limitations which are not present in the pending claims. The Examiner discounts the limitation that the claimed polynucleotides encode a polypeptide comprising a naturally occurring amino acid sequence or comprise a naturally occurring polynucleotide sequence.

The Examiner stated that "[i]f Appellants desire a variant of a polynucleotide encoding SEQ ID NO:2 or having SEQ ID NO:9, then functional language will be placed into the claim so that one skilled in the art has an assayable activity to determine if their polynucleotides is [*sic*] anticipated by Appellants." (Examiner's Answer, page 3.) The Examiner stated that "[t]he written description guidelines at Example 14 specifically require that both structure and function will be provided when a variant of a polynucleotide (or other compound) is claimed." (Examiner's Answer, page 4, underline added.)

Appellants disagree that one skilled in the art would not recognize that Appellants were in possession of the recited variants of SEQ ID NO:2 and SEQ ID NO:9. Appellants further disagree that the written description guidelines require an association of structure with function in claiming such variants. The Examiner has merely cited an Example in the "Synopsis of Application of Written Description Guidelines" (the Training Materials for the written description guidelines) which includes a functional limitation as one means of satisfying the written description guidelines.

The Examiner's position is clearly contrary to the USPTO's own written description guidelines ("Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1", published January 5, 2001), which provide that:

> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence

> that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. **What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described** in the specification, then the adequate description requirement is met. (citations omitted, emphasis added)

Here, there simply is no requirement that the claims recite particular variant polypeptide or variant polynucleotide sequences because the claims already provide sufficient structural definition of the claimed subject matter. That is, the polypeptide variants are defined in terms of SEQ ID NO:2 ("An isolated polynucleotide encoding a polypeptide selected from the group consisting of. . . b) a polypeptide comprising a naturally occurring amino acid sequence having at least 90% sequence identity to an amino acid sequence of SEQ ID NO:2." The polynucleotide variants are defined in terms of SEQ ID NO:9 ("An isolated polynucleotide selected from the group consisting of . . . b) a polynucleotide comprising a naturally occurring polynucleotide sequence having at least 90% sequence identity to a polynucleotide sequence of SEQ ID NO:9.").

Because the recited polypeptide variants are defined in terms of SEQ ID NO:2, and the recited polynucleotide variants are defined in terms of SEQ ID NO:2 and SEQ ID NO:9, the precise chemical structure of every polypeptide variant and every polynucleotide fragment within the scope of the claims can be discerned. The Examiner's position is nothing more than a misguided attempt to require Appellants to unduly limit the scope of their claimed invention. Accordingly, the Specification provides an adequate written description of the recited polypeptide and polynucleotide sequences.

II. The Examiner alleges that "the specification does not teach polynucleotides encoding a polypeptide have [*sic*] 90% identity to SEQ ID NO:2 or polynucleotides that are 90% identical to SEQ ID NO:9 and encode a polypeptide having any function." (Examiner's Answer, page 4.) However, the Specification teaches that:

> An "allele" or "allelic sequence", as used herein, is an alternative form of the gene encoding DAPK. Alleles may result from at least one mutation in the nucleic acid sequence and may result in **altered mRNAs or polypeptides whose structure or function may or may not be altered**. (Specification, page 9, lines 17-20, emphasis added.)

III. The Examiner further alleges that the Specification does not provide "correlation of structure with function." (Examiner's Answer, page 4.) However, functional limitations are not necessary as the structural and source limitations are sufficient to describe the recited polypeptide variants and polynucleotide variants. In any case, "function" is irrelevant to the use of the recited polypeptide variants and polynucleotide variants, e.g., in toxicology testing (see for example, Specification, page 41, line 23 through page 47, line 9 and page 48, lines 9-27).

IV. In the Appeal Brief Appellants cited two scientific journal articles, Brenner et al., and Hegyi et al. (Appeal Brief, pages 8-9.) The Examiner in the Examiner's Answer states that "Appellants . . . discuss new references, Brenner et al. and Hegyi et al. without benefit of making these references official by filing them with an Information Disclosure Statement (PTO-1449)." (Examiner' s Answer, page 5.) Appellants note first that the MPEP requires that the Examiner consider timely submitted references, regardless of whether or not they are included in an Information Disclosure Statement. MPEP in § 609, part III. C(3) "Documents Submitted As Part of Applicant's Reply to Office Action" that:

> Occasionally, documents are submitted and relied on by an applicant when replying to an Office action. These documents may be relied on by an applicant, for example, to show that an element recited in the claim is operative or that a term used in the claim has a recognized meaning in the art. Documents may be in any form but are typically in the form of an affidavit, declaration, patent, or printed publication.
>
> To the extent that a document is submitted as evidence directed to an issue of patentability raised in an Office action, and the evidence is timely presented, applicant need not satisfy the requirements of 37 CFR 1.97 and 37 CFR 1.98 in order to have the examiner consider the information contained in the document relied on by applicant. In other words, compliance with the information disclosure rules is not a threshold requirement to have information considered when submitted by applicant to support an argument being made in a reply to an Office action.

Furthermore, the Brenner et al. journal article is not a "new" reference, having been first submitted with the Response to Non-Final Office Action filed February 3, 2003. The Final Office Action mailed April 15, 2003 did not acknowledge or address the Brenner et al. journal article.

For at least the above reasons, reversal of the written description rejection is requested.

CONCLUSION

For all the foregoing reasons and the reasons stated in Appellants' Brief on Appeal, it is submitted that the Examiner's rejections of the claims on appeal should be reversed.

If the USPTO determines that any additional fees are due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

This brief is enclosed in triplicate.

Respectfully submitted,
INCYTE CORPORATION

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